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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/226,597	01/07/1999	JULIO PIMENTEL	ANIT0018U-US	9844

31518 7590 02/09/2007

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EXAMINER	
GABEL, GAILENE	
ART UNIT	PAPER NUMBER
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/226,597	PIMENTEL, JULIO	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-5 and 12-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 12-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 28, 2006 has been entered.

Claim Objections

2. It is noted that the numbering of claims is not in accordance with 37 CFR 1.126 which requires the original correct numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

In this case, two claims have been assigned as claim 22. Accordingly, misnumbered claims: claim 22, first occurrence, claim 22, second occurrence, and claims 23-41 thereafter have been renumbered as claims 23-42, respectively. Their corresponding dependencies have also been corrected accordingly. From here on, each of the claims will be referenced in accordance to their corrected numbering.

Please acknowledge that this correction has been made to your records, and note such correction in Applicant's response to this Office Action.

Amendment Entry

3. Applicant's amendment and response filed on July 14, 2006 is acknowledged and has been entered. Claims 17, 24, and 36-42 have been amended. Currently, claims 1-5 and 12-42 are pending. Claims 1-5 and 12-42 are under examination.

Rejections Withdrawn

4. All rejections not reiterated herein have been withdrawn.

5. In light of Applicant's argument, the rejection of claims 1-5 and 12-42 under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US Patent 5,919,451) in view of Drent et al. (Lipase inhibition: a novel concept in the treatment of obesity, International Journal of Obesity 17: 241-244 (1993)) and in further view of LeClercq et al. (Metabolism of very low density lipoproteins in genetically lean or fat lines of chicken, Reproduction, Nutrition, Development, 30 (6): 701-715 (1990)), is hereby, withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 3, 12, 20, 21, 34, 35, and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite in reciting method steps of making a composition which depends from a method of using a composition. Accordingly, it is unclear how the method steps in claim 3 should cooperatively, structurally, and functionally apply to claim 1 from which it depends.

Claim 12 is indefinite in reciting method steps of making a composition which depends from a method of using a composition. Accordingly, it is unclear how the method steps in claim 12 should cooperatively, structurally, and functionally apply to claim 1 from which it depends.

Claim 20 recites intended use for the composition recited in claim 16 from which it depends. Accordingly, claim 20 is indefinite in not further limiting claim 16 from which it depends.

Claim 21 recites intended use for the composition recited in claim 16 from which it depends. Accordingly, claim 21 is indefinite in not further limiting claim 16 from which it depends.

Claim 34 is indefinite in reciting method steps of making a composition which depends from a method of using a composition. Accordingly, it is unclear how the method steps in claim 33 should cooperatively, structurally, and functionally apply to claim 31 from which it depends.

Claim 35 is indefinite in reciting method steps of making a composition which depends from a method of using a composition. Accordingly, it is unclear how the method steps in claim 34 should cooperatively, structurally, and functionally apply to claim 31 from which it depends.

Claim 42 is indefinite in reciting, "A method of using a composition", albeit "formed by a process ..." because the claim is drawn to a method of using a composition *already formed*, whereas "providing a solution", and "adding liposomes ... to make a solution" encompass a method of forming. Accordingly, it is unclear how these method of forming steps should cooperatively, structurally, and functionally apply to the actual method of use step in the claim.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. For purposes of prior art rejection, the claims, as written, are interpreted as follows. Note that unpatented claims are given the broadest reasonable interpretation consistent with the specification.

A. Claims 1-5, 12-15, 32-35, and 42 are method of use claims as follows:

Claims 1-5 and 12-15 are drawn to a method: feeding an animal food and liposome-encapsulated anti-lipase antibodies.

Claims 32-35 and 42 are drawn to a method: feeding an animal liposome-encapsulated anti-lipase antibodies.

B. Claims 16-24, 26-28, and 39-41 are product/composition claims as follows:

Claims 16-24 are drawn to a composition: mixture of food an liposome-encapsulated anti-lipase antibodies.

Claims 26-28 are drawn to a composition: liposome-encapsulated anti-lipase antibodies.

Claims 39-41 are drawn to a composition: liposomes and anti-lipase antibodies in a solution.

C. Claims 25, 29-31, and 36-38 are method of making claims as follows:

Claim 25 is drawn to a method of making a composition: mixture of food and liposome-encapsulated anti-lipase antibodies.

Claims 29-31 are drawn to method of making a composition: liposome-encapsulated anti-lipase antibodies.

Claims 36-38 are drawn to making a composition: a solution containing liposomes and anti-lipase antibodies.

From here on, liposome-encapsulated anti-lipase antibodies are LE anti-lipase Abs.

8. Claims 1-5 and 12-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US Patent 5,919,451) in view of LeClercq et al. (Metabolism of very low density lipoproteins in genetically lean or fat lines of chicken, Reproduction, Nutrition, Development, 30 (6): 701-715 (1990)).

Cook et al. disclose a method of feeding to an animal a food composition comprising a liposome-encapsulated antibody (see column 1, line 1 to column 2, line 6). The antibody may be provided in solution in a wet state, in an aqueous or lipid carrier, i.e. liposome-encapsulation, and may also be directly applied to the pellet core without a carrier (freeze-dried) such as a powder. The antibody is, however, preferably encapsulated in liposome (see column 2, lines 22-46). The antibody is avian, i.e. obtained from egg of a hen which has been injected with antigen that results to the production of its corresponding antibodies (see column 1, lines 44-53 and column 3, lines 1-14). The food composition is made by forming a nutrient mixture and then depositing the liposome-encapsulated antibody into the pellet core (see column 2, lines 12-21). The food content comprises protein and carbohydrate may also include vitamins and dietary lipid (column 2, lines 54-67 and column 4, lines 1-19). The food composition and method are prepared as animal feed for use in either mammals (pets),

or avians such as ducks, chickens, and turkeys (see column 6). The food composition containing the avian antibody is fed to the animal in an amount that may be effective in passively immunizing the animal or otherwise enhancing the efficiency of feed conversion by the animal (column 3, lines 1-4). The antibodies may be any one which can which can alter physiological processes that adversely affect growth and efficiency. The antibodies can be those that are against diseases or specific for endogenous antigens present in the digestive system that regulate food intake and gastrointestinal motility (see column 1, line 62 bridging to column 2, line 6; and column 3, lines 5-9).

Cook et al. differ from the claimed invention in failing to teach that the antibody is anti-lipase antibody directed against lipase antigen.

LeClercq et al. teach anti-lipoprotein lipase antibodies against lipase antigen and their use in completely inhibiting lipase activity in fat lines and lean lines of chickens (see page 703, column 2 to page 704, column 1). At page 705, column 2 to page 706 and page 709, column 2 to page 711, LeClercq confirmed that anti-lipoprotein antibodies are able to inhibit lipoprotein lipase activity, and conclude that difference in fatness is not due to difference in feed intake but to metabolic deviations depending on hormonal control. Although LeClercq is silent in teaching that lipase antigen is present in the gastrointestinal system (or gut), it is well known that lipase antigen is a gastrointestinal enzyme that is inherently produced by the pancreas which hydrolyzes triglycerides into free fatty acids and glycerol, hence, important in breaking down ingested fat in the gastrointestinal system.

It would have been obvious to one of ordinary skill in the art at the time of the

instant invention to substitute the anti-lipase antibodies as taught by LeClercq that are specific for lipase antigen produced in the gut, for the antibodies that are liposome encapsulated taught in the method of Cook, that are also specific for antigens present in the gut such as CCK, for feeding to animals in solution or as feed composition, because anti-lipase antibodies specific for lipase antigen as taught by LeClercq and CCK antibodies specific for CCK antigen as taught by Cook, constitute obvious variations of antibodies specific for antigens known in the art, to be produced and inherently present in the gut, and that Cook specifically taught that they can be liposome-encapsulated for incorporation with food intake.

Cook et al. and LeClercq et al. do not disclose that the composition contains 25 to 1000 mg of liposome encapsulated anti-lipase antibodies per kilogram of the animal food, as recited in claims 14, 15, 17, and 23.

Cook et al. specifically disclose administering safe and effective amounts of antibody that would help protect the animal from disease or other antigens that can adversely affect animal's growth or the efficiency of the animal to convert feed into desirable body tissue. Therefore, the amount of liposome-encapsulated anti-lipase antibody contained in a food composition should be a safe and effective quantity.

Such ranges of antibody concentrations in food composition, are rendered as result effective variables, which the prior art references have shown may be altered in order to achieve optimum results. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a

result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233,235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215,218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in claims 14, 15, 17, and 23 are for any particular purpose or solve any stated problem and the prior art teaches that effective concentrations of antibodies or compounds used may vary according to the animals being fed and/or their characteristics, absent unexpected results, it would have been obvious for one of ordinary skill to discover the safe and effective amounts of antibodies and compounds used for the composition and method disclosed by the prior art by normal optimization procedures.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 2, 16, 18, 19, 26-28, 32, and 33 are provisionally rejected on the ground of nonstatutory double patenting over claims 1, 8, 14, 18, 31, 47, and 51 of copending Application No. 08/888,202. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: anti-lipase antibodies for incorporation into food intake.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

10. Claims 1, 2, 16, 18, 19, 26-28, 32, and 33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over

claims 1, 8, 14, 18, 31, 47, and 51 of copending Application No. 08/888,202 in view of Cook et al. (US Patent 5,919,451). Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications recite feeding to an animal, anti-lipase antibodies incorporated with a feed.

Application No. 08/888,202 differ from the instant invention in failing to recite and teach incorporating the anti-lipase antibodies into liposome for encapsulation.

Cook et al. is discussed supra. Specifically, Cook et al. disclose a method of feeding to an animal a food composition comprising a liposome-encapsulated antibody. The antibody may be provided in solution in a wet state and may also be directly applied to the pellet core without a carrier (freeze-dried) such as a powder. The antibody is avian, i.e. obtained from egg of a hen which has been injected with antigen that results to the production of its corresponding antibodies. The antibodies can be those that are against diseases or specific for endogenous antigens present in the digestive system that regulate food intake and gastrointestinal motility.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the anti-lipase antibodies in Application No. 08/888,202, into liposomes for encapsulation as taught in the method of Cook, because Cook taught that liposome encapsulation helps protect the antibodies that are fed, from stomach acids and intestinal enzymes that destroy them and their efficacy (see Cook et al. at column 2, lines 41-46).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

11. Applicant's arguments with respect to claims 1-5 and 12-42 based on the combination of Cook et al. with Drent et al. and LeClercq et al. have been considered but are moot in view of the new grounds of rejection.

12. Applicant's arguments in regards to relevancy of the Cook et al. reference in combination with the LeClercq et al. reference filed on December 28, 2006 have been considered but are not persuasive.

A) Applicant argues that claim 3 is definite because it broadly recites "A method comprising" which does not limit the claim to a single method of making or a single method of using. Applicant specifically contends that claim 3 simply recites, "A method comprising" and therefore, any additional number of steps are within the scope of claim 1, and the additional step defined by claim 3 of "storing" is a proper additional limitation to the subject matter defined by claim 1.

In response, Examiner concedes that Applicant is not limited to any number of method steps recited to further limit a claim, regardless of the transitional phrase used to limit the scope of the recited claims. However, since claim 1 recites method steps that are drawn to a method of using anti-lipase antibodies, the method steps of making the anti-lipase antibodies that are subsequently recited cannot be construed to clearly define the metes and bounds of the originally recited method of using in claim 1. Accordingly, claim 3 does not further limit the method of claim 1 since it defines an

entirely different method, i.e. method of making the LE anti-lipase Abs, from the original set of method steps recited in claim 1 from which it depends, which encompasses a method of using the LE anti-lipase Abs. Same analogous comments and problems apply to claim 12.

In as far as claim 42 as amended, the preamble recites, "A method of using a composition", albeit "formed by a process ..." so that "providing a solution", and "adding liposomes ... to make a solution" encompass method steps of forming, which therefore do not further limit the actual scope of the claim. Accordingly, it is unclear how the recited method steps of forming should functionally apply to the actual method of use intended for the claim.

B) Applicant argues that Cook does not disclose feeding anti-lipase antibodies; the only actual antibody disclosed in Cook is antibody to Cholecystokinin (CCK) and that the only antigen disclosed in Cook is CCK and that all of Cook's examples show feeding antibody to CCK to reduce weight gain. Applicant specifically contends that the goal and effect of the instant application is to feed LE anti-lipase Abs in order to decrease feed conversion efficiency and reduce weight gain, and increase weight loss, which is contradictory to Cooks goal and effect which is to inhibit physiological processes that adversely affect growth and efficiency, with results shown to be "increased feed conversion efficiency and weight gain".

In response to applicant's arguments against the Cook et al. singly as a reference failing to show feeding LE anti-lipase Abs, one cannot show nonobviousness

by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the rejection is based on the combined teaching of Cook et al. with LeCLercq et al. to render the claimed invention obvious. As recited, the claims simply recite *feeding [previously formed] composition or food mixture comprising LE anti-lipase antibodies to animals.* Accordingly, Cook et al. teach encapsulating avian antibodies to gut antigens for incorporation into feed for intake, albeit exemplifying mostly CCK. LeCLercq et al. is relied upon for combination with Cook et al. for teaching anti-lipase antibodies which are specific for lipase antigens that are inherently present in the gut. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute the anti-lipase antibodies as taught by LeClercq that are specific for lipase antigen produced in the gut, for the antibodies that are liposome encapsulated taught in the method of Cook, that are also specific for antigens present in the gut, for feeding to animals as feed composition, because anti-lipase antibodies specific for lipase antigen and CCK antibodies specific for CCK antigen, constitute obvious variations of antibodies specific for antigens known in the art, to be produced and inherently present in the gut, and that Cook specifically taught that they can be liposome-encapsulated for incorporation with food intake.

In response to Applicant's contention that Cook does not teach anti-lipase antibodies and only CCK antibodies, it is reiterated that the rejection is not based on an anticipation rejection using only a single prior art. The rejection is based on an

obviousness rejection using Cook in combination with LeClercq who is relied upon for teaching anti-lipase antibodies.

In response to applicant's argument that Cook is nonanalogous art in teaching feeding CCK rather anti-lipase antibodies, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the method of use claims recited in claims 1-5, 12-15, 32-35, and 42, simply recite "feeding an animal ... LE anti-lipase Abs" which are antibodies specific for an antigen in the gut, and is analogous to Cook's reference which discloses feeding an LE-antibody specific to another variation of antigen, i.e. CCK, in the gut. Hence, Cook teaches analogous art and provides suggestion of applicability of liposome encapsulation with other antibodies specific for other physiological antigens present in the gut.

In response to applicant's argument that the Cook reference fails to show certain features of applicant's invention (i.e., feeding LE anti-lipase Abs decrease conversion efficiency, reduce weight gain, and increase weight loss) which encompass the goal and effect intended in Applicant's disclosure, it is noted that such features upon which applicant rely are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims simply recite, *feeding [previously formed] composition or food mixture comprising LE*

anti-lipase antibodies to animals. Hence, the statement of intended goal and effect by the LE anti-lipase Abs in Applicant's response, cannot be construed to have patentable weight.

C) Applicant argues that LeCLercq teaches intravenously injecting LPL antibody into chicken to suppress LPL in the chickens and that LeCLercq teaches only feeding birds low fat diets; hence, LeClercq et al. is non-analogous art because it does not teach feeding or orally administering the anti-lipase antibodies to the chickens. Applicant specifically contends that LeClercq et al. relates only to the effect of antibodies in the blood, not in the gut. Applicant then argues that the LeClercq et al. reference provides no teaching relevant to Cook et al. because there is no teaching or suggestion of efficacy in making and feeding anti-lipase antibodies, so as to modify the teaching of Cook et al.

In response to applicant's arguments against the LeClercq et al. singly as a reference failing to show feeding anti-lipase antibodies to chickens, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the rejection is based on the combined teaching of Cook et al. with LeCLercq et al. to render the claimed invention obvious. As recited, the claims simply recite *feeding [previously formed] composition or food mixture comprising LE anti-lipase antibodies to animals.* Accordingly, Cook et al. is used as primary reference for teaching

encapsulating avian antibodies to gut antigens for incorporation into feed for intake, albeit exemplifying mostly CCK. LeCLercq et al. is only relied upon for combination with Cook et al. for teaching anti-lipase antibodies which are specific for lipase antigens that are inherently present in the gut. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute the anti-lipase antibodies as taught by LeClercq that are specific for lipase antigen produced in the gut, for the antibodies that are liposome encapsulated taught in the method of Cook, that are also specific for antigens present in the gut, for feeding to animals as feed composition, because anti-lipase antibodies specific for lipase antigen and CCK antibodies specific for CCK antigen, constitute obvious variations of antibodies specific for antigens known in the art, to be produced and inherently present in the gut, and that Cook specifically taught that they can be liposome-encapsulated for incorporation with food intake.

In response to applicant's argument that the LeClercq et al. reference fails to show certain features of applicant's invention (i.e., LeClercq et al. does not suggest decreasing conversion efficiency, reducing weight gain, and increasing weight loss by way of anti-lipase antibodies fed to animals) which encompass the goal and effect intended in Applicant's disclosure, it is noted that such features upon which applicant rely are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims simply recite, *feeding [previously formed] composition or food mixture comprising LE anti-*

lipase antibodies to animals. Hence, the statement of intended goal and effect by the anti-lipase antibodies fed to animals, are not given patentable weight.

D) Applicant argues that the Cook et al. patent used as a prior art reference, and the other patents related thereto are not enabled in as far as effectiveness of antibodies generated in eggs in response to anti-nutritional factors injected into hens. Applicant contends that the conclusion reached by Examiner of Cook's related application US Patent 5,725,873 are contrary to the obviousness conclusion reached by the previous Office Action of the instant application. The issues addressed in US Patent 5,725,873 are enablement issues regarding the scope of antibodies outside CCK antibodies.

First and foremost, issues within prosecution history of other granted patents of Cook et al. including the patent reference of record, do not have bearing on the issues at hand, in this or other patent applications. Specifically, patents when granted are presumed to be enabled under the provisions of 35 US 112, first paragraph. In as far as the purpose of goal and effect of the antibodies taught in the Cook et al. reference being contradictory and non-enabling or enabled only to CCK antibodies in comparison to the claimed invention, it is noted that such issues of goal and effect desired after feeding LE anti-lipase Abs, are not recited in the rejected claims. The claims simply recite *feeding [previously formed] composition or food mixture comprising LE anti-lipase antibodies to animals,* and there do not appear to be any enablement issues or problems in encapsulating antibodies to gut antigens, adding them to feed to form a food composition, then feeding them to animals, as claimed. In as far as the statement of

goal and effect intended for the claimed invention to achieve by liposome encapsulating anti-lipase antibodies and feeding it to animals, such recitations of desired goal and effect, i.e. decrease feed conversion efficiency, reduce weight gain, and increase weight loss, are lacking in the claims, and therefore, cannot be construed to have patentable weight. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

E) Applicant argues that US Patent 5,919,451 Cook et al. reference, is not prior art because the inventor of the instant application originally filed substantially the same disclosure as contained in ASN 08/888,202, filed on July 7, 1997.

In response, Applicant's argument is not persuasive because the instant application does not claim the benefit of priority of ASN 08/888,202. Accordingly, the benefit of priority of the instant application is its effective filing date. Alternatively, even if the instant application would have claimed the benefit of priority of ASN 08/888,202 which is July 7, 1997, since the Cook et al. patent (US Patent 5,919,451) was a CIP application claiming the benefit of priority of US Patent 5,725,873 filed on July 22, 1996 which substantially discloses the subject matter in Cook's US Patent 5,919, 451, it is determined that the Cook et al. patent reference of record, is still prior art over the instant application.

Response to Inventor's 37 CFR 1.131 Declaration

13. Applicant's declaration with respect to claims 1-5 and 12-42 in reference to the combination of Cook et al. with LeClercq et al. are acknowledged herein.

A) Applicant states that he is the inventor of ASN 08/888,202 filed on July 7, 1997, which discloses subject matter consonant to the instant application. Applicant states that in ASN 08/888,202, Example 7 shows preparation of LE anti-lipase Ab and Example 8-10 show the antibody's use in feeding animals and effectiveness in inhibiting lipase action in animals.

In response, Examiner concurs that LE anti-lipase Abs and its use are disclosed in ASN 08/888,202. However, it is noted that the instant application does not claim the benefit of priority of ASN 08/888,202. Accordingly, the benefit of priority of the instant application is its effective filing date. Alternatively, even if the instant application would have claimed the benefit of priority of ASN 08/888,202 which is July 7, 1997, since the Cook et al. patent (US Patent 5,919,451) was a CIP application claiming the benefit of priority of US Patent 5,725,873 filed on July 22, 1996 which substantially discloses the subject matter in Cook's US Patent 5,919, 451, it is determined that the Cook et al. patent reference of record, is still prior art over the instant application.

Response to Inventor's 37 CFR 1.132 Declaration

14. Applicant's declaration with respect to claims 1-5 and 12-42 in reference to the combination of Cook et al. with LeClercq et al. are acknowledged herein.

A) Applicant states that he has reviewed US Patent 5,827,517, US Patent 5,989,548, and US Patent 6,793,921 and provides that the tests presented therein show no efficacy for antibodies other than CCK. According to Applicant, the data in the patents show that some antibody treatments were effective and others were not in achieving their desired results.

In response, the statements of goal and effect of the antibodies and nutritional values taught in the Cook et al. references not of record, being non-enabling or enabled only to CCK antibodies in comparison to the claimed invention, are not on point with the current issues at hand because the recited claims do not seek to obtain any particular result. It is specifically noted that the goal of the claimed method and its effect desired after feeding LE anti-lipase Abs, are not recited in the rejected claims. The claims simply recite *feeding [previously formed] composition or food mixture comprising LE anti-lipase antibodies to animals,* and there do not appear to be any enablement problems in encapsulating antibodies to gut antigens such as lipase, adding them to a feed composition to form a mixture, then feeding them to animals, as claimed. In as far as the statement of goal and effect intended for the claimed invention to achieve results such as 1) decrease feed conversion efficiency, 2) reduce weight gain, and 3) increase weight loss, such limitations are lacking in the recited claims, and therefore, cannot be construed to have patentable weight. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gailene R. Gabel
Patent Examiner
Art Unit 1641
January 31, 2007